UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,814	10/23/1998	TERRY L. GILTON	353OUS(97-12	3621

7590 10/21/2003

JOSEPH A WALKOWSKI
TRASK BRITT & ROSSA
P O BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	29

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/177,814	GILTON, TERRY L.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Appellant's Brief filed 6/16/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13-44,46,48-64,66-74 and 105-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33,63,74,and 105- 107* is/are allowed.

6)☒ Claim(s) *1,3-11,13-32,34-44,46,48-62,64 and 66-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Appellant's Brief

1. In view of the Appellant's Brief filed on 5/27/03, PROSECUTION IS HEREBY REOPENED. A non-final office action is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Currently, claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 102/103

3. In light of Applicant's argument, the rejection of claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 under 35 U.S.C. 103(a)

as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) is hereby, withdrawn.

4. In light of Applicant's argument, the rejections of claims 6, 8, 14-15, 17, 21-24, 26-28, 33, 35-37, 40-42, 44, 54-55, 57-63, 66-68, 72, and 74 under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, in further view of Swedberg et al. (US 5,571,410), Miura et al. (US 5,132,012), Northrup et al. (US 5,882,496), Sunzeri (US 5,536,382), and Crenshaw et al. (US 5,726,085) are hereby, withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 51, 64, 66, and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Northrup et al. (US 5,882,496).

Northrup et al. disclose porous silicon electrophoresis and control flow devices. Porous silicon increases surface area and also increases gas or fluid flow in flow

channel structures designed to capture (adsorb, separate or filter) biological particles from a sample (see Abstract and column 7, lines 38-50). Northrup et al. specifically disclose that porous silicon which is fabricated from crystalline silicon have very small pore diameters so that they can be produced with relatively high degree of uniformity and control (see column 1, lines 27-55). Porosity is formed by electrochemical etching to form small pores in the bulk silicon (see column 3, lines 54-60). Figure 8 illustrates an electrophoresis device having formed thereon, multiple, distinct, unconnected porous silicon columns or spaced members. A negative electrode is formed at one end (inlet) of the porous silicon columns and a positive electrode is formed at an opposite end (outlet) of the porous silicon columns, thereby forming microelectrophoresis channels (see column 7, lines 38-50). These electrodes or migration facilitators within or adjacent the porous membrane are used to control flow of specific electrically charged biochemical species (see column 5, lines 21-67). Because of its high surface area and specific pore size, porous silicon is utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being doped or coated using conventional integrated circuit and micromachining (see Summary).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. (US 5,882,496) in view of Swedberg et al. (US 5,571,410).

Northrup et al. have been discussed supra. Northrup et al. differ from the instant invention in failing to teach antibody or antigen as the capture or filter substrate for the device.

Swedberg et al. teach a miniaturized planar column device for integrated sample analysis of analytes (see column 8, lines 5-38). Swedberg et al. specifically teach a capture substrate which performs a filtration function filled with a biocompatible porous medium of particles into which a capture function has been incorporated therein (see column 27, lines 33-61 and Example 1). Specifically, Swedberg teaches that the capture species (biological affiants) include antibodies, antigens, lectin, enzyme etc. (see column 27, lines 43-61 and Example 1). Swedberg et al. also disclose a "LIGA"

process which is used to refer to a process of fabricating microstructures having high aspect ratios and increased structural precision in order to create desired uniformity in microstructures such as channel ports, apertures, and microalignment means (see column 13, lines 9-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute antibody or antigen as taught by Swedberg, into the electrophoresis device having multiple columns as taught by Northrup in order to achieve performance of both filtration and capture function because Swedberg specifically suggested potential application of his teachings in monitoring biological analyses as applied to miniaturized controlled flow devices such as the electrophoresis device taught by Northup.

7. Claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 22-25, 29-32, 34, 38, 39, 42, 43, 46, 48-50, 52, 53, 56, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Northrup et al. (US 5,882,496).

Isaka et al. disclose a chromatograph apparatus comprising a microchannel element formed on a semiconductor substrate. Specifically, the apparatus includes a semiconductor substrate and a matrix (microchannel) which extends across the substrate. The semiconductor substrate comprises of silicon (see column 6, lines 5-7). The matrix is formed with a desired pattern, i.e. linear, circular, on the semiconductor substrate by incorporating a porosity thereon in order to create a porous portion with increased pore size and extended branching of the pores on the semiconductor surface

(see Abstract and column 1, lines 35-46). The length of the matrix channel is not limited although its length is preferably larger than its diameter (see column 2, lines 18-25). The porosity is preferably 10-90% (see column 2, lines 60-63). Optimal pore size and pore shape can be achieved in accordance with the substance to be separated and measured, i.e. selecting the type and concentration of a dopant (see column 3, lines 35-42). A thin semiconductor substrate layer may be formed by ion injection after formation of a silicon dioxide layer by thermal oxidation (see column 4, lines 53-55). The apparatus is applicable for use in solid-gas separation, solid-liquid separation, liquid-liquid separation, and gaseous separation. The separation makes use of the difference in flow rate between gases and liquids or in reactions (enzyme reaction) involving capture substrate (absorptivity involving immobilized enzyme) (see column 3, lines 1-14 and 50-54). In liquid chromatographs, an inlet port of the apparatus is coupled to a pump (migration facilitator) into the porous channel to identify difference in elution time between two liquids using differential refractometer (see column 5, lines 17-29). Isaka et al. also disclose ion column detection performed on a capillary, i.e. absorption detector (see column 3, lines 16-24). Finally, Isaka et al. teach incorporation of a sealing element (cover) consisting of a single-crystal silicon film on the silicon substrate on which the matrix is formed (see column 5, lines 38-49).

Isaka et al. differ from the instant invention in failing to teach forming at least two porous microchannels in the silicon substrate. Isaka et al. further differs from the instant invention in failing to teach the migration facilitator as comprising electrodes disposed into the porous region of the chromatograph.

Northrup et al. disclose porous silicon electrophoresis and control flow devices. Porous silicon increases surface area and also increases gas or fluid flow in flow channel structures designed to capture (adsorb, separate or filter) biological particles from a sample (see Abstract and column 7, lines 38-50). Northrup et al. specifically disclose that porous silicon which is fabricated from crystalline silicon have very small pore diameters so that they can be produced with relatively high degree of uniformity and control (see column 1, lines 27-55). Porosity is formed by electrochemical etching to form small pores in the bulk silicon (see column 3, lines 54-60). Figure 8 illustrates an electrophoresis device having formed thereon, multiple, distinct, unconnected porous silicon columns or spaced members. A negative electrode is formed at one end (inlet) of the porous silicon columns and a positive electrode is formed at an opposite end (outlet) of the porous silicon columns, thereby forming microelectrophoresis channels (see column 7, lines 38-50). These electrodes or migration facilitators within or adjacent the porous membrane are used to control flow of specific electrically charged biochemical species (see column 5, lines 21-67). Because of its high surface area and specific pore size, porous silicon is utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being doped or coated using conventional integrated circuit and micromachining (see Summary).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate multiple porous silicon columns as taught by Northrup

into the miniaturized chromatograph apparatus of Isaka because Northrup specifically taught multiple columns because duplication of parts such as in this case, columns in separation flow devices, is conventional and well within ordinary skill. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate electrodes such as taught by Northrup into the miniaturized silicon device taught by Isaka because Northrup specifically taught application of electrodes into miniaturized porous silicon structures in electrophoresis devices or such as in the miniaturized separation device taught by Isaka.

8. Claims 8, 26-28, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Northrup et al. (US 5,882,496) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 22-25, 29-32, 34, 38-39, 42, 43, 46, 48-50, 52, 53, 56, and 69-71 above, in further view of Swedberg et al. (US 5,571,410).

Isaka et al. and Northrup et al. have been discussed supra. Isaka et al. and Northrup et al. differ in failing to teach antibody or antigen as the capture substrate for the miniaturized chromatograph.

Swedberg et al. teach a miniaturized planar column device for integrated sample analysis of analytes (see column 8, lines 5-38). Swedberg et al. specifically teach a stationary phase (sample treatment component) which performs a filtration function filled with a biocompatible porous medium of particles into which a capture function has been incorporated therein (see column 27, lines 33-61 and Example 1). Specifically, Swedberg teaches a stationary phase incorporated into a miniaturized affinity

chromatography column onto which separation and capture functions are combined; the capture species (biological affiants) include antibodies, antigens, lectin, enzyme etc. (see column 27, lines 43-61 and Example 1). Swedberg et al. also disclose a "LIGA" process which is used to refer to a process of fabricating microstructures having high aspect ratios and increased structural precision in order to create desired uniformity in microstructures such as channel ports, apertures, and microalignment means (see column 13, lines 9-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stationary phase in the porous matrix taught by Isaka, having multiple columns as modified by Northrup, to include antigens and antibodies as taught by Swedberg in order to achieve performance of both filtration and capture function because Swedberg specifically suggested potential application of his teachings in monitoring biological analyses as applied to liquid phase separation devices in the miniature scales such as the device taught by Isaka. One of ordinary skill in the art would have been motivated to incorporate the teachings of Isaka as modified by Northrup, with biocompatible modification as taught by Swedberg because both of Isaka and Northrup specifically taught that porous silicon has established porosity with enhanced capacity for separation, augmented adsorption, differentiation of flow rate in liquid or gaseous samples, thereby producing a highly versatile miniaturized chromatographic device capable of both enhanced partitioning and complexation reactions.

9. Claims 14-15, 17, 21, 40-41, 44, and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Northrup et al. (US 5,882,496) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 22-25, 29-32, 34, 38-39, 42, 43, 46, 48-50, 52, 53, 56, and 69-71 above, and further in view of Miura et al. (US 5,132,012).

Isaka et al. and Northrup et al. have been discussed supra. Isaka et al. and Northrup et al. differ from the instant invention in failing to teach incorporating a field effect transistor detector, memory device, and controls into the apparatus.

Miura et al. disclose a miniaturized sample separator in the form of a liquid chromatograph comprising an analyzing chip in which the capillary flowpath is formed in a substrate and a field effect transistor detector disposed downstream of the capillary (see Abstract). The substrate is made of silicon and further has an insulative membrane formed of silicon dioxide (see column 3, line 51 to column 4, line 7). Both the column for separation and the field effect transistor detector are formed integrally with the substrate. After the silicon oxide layer has been formed on the capillary groove, a stationary phase is formed. A valve is connected to a first end of the flow path in the sample application area (sample introduction pipe) where a sample is selectively introduced into the flowpath. A separation carrier solution (carrier gas/ vacuum source) is fed under pressure by a feed pump and then discharged from a drain after having passed through the flowpath. Miura et al. further teach a sealing element (seal plate) such as borosilicate glass for sealing the opening portion of the groove portion to define the flow passage for a liquid sample. The liquid chromatograph also

comprise a memory (control) device and an output device such as a data processor which is connected to the detector for detecting separated constituents (see column 5, line 63 to column 6, line 22). Figures 4A and 4B illustrate an electrical conductivity detector which comprise voltage application and current detection components, i.e. electrodes. Figure 9 shows a schematic view of the overall flow passage of the liquid chromatograph.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate field effect transistor detector, memory device, and controls as taught by Miura into the miniaturized chromatograph apparatus with porous silicon channels such as taught by Isaka as modified by Northrup, because Miura specifically taught application of such elements into miniaturized chromatographic devices such as taught by Isaka and Northrup. One of ordinary skill in the art at the time of the invention would have been motivated to combine the teaching of Miura into the chromatograph device of Isaka as modified by Northrup, because Miura recognized and solved technical difficulties in miniaturizing analyzers by incorporating these necessary elements into his device (rather than providing them independently of each other).

10. Claims 6, 57-62, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Northrup et al. (US 5,882,496) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 22-25, 29-32, 34, 38-39, 42, 43, 46, 48-50, 52, 53, 56, and 69-71 above, and in further view of Sunzeri (US 5,536,382).

Isaka et al. and Northrup et al. have been discussed supra. Isaka et al. and Northrup et al. differ from the instant invention in failing from the instant invention in failing to incorporate a control column into the separation devices comprising porous silicon.

Sunzeri discloses analysis of constituents of human biological fluids using capillary electrophoresis. Sunzeri specifically teaches the use of standard control to provide a standard for quantitation (see column 9, lines 28-67). Sunzeri further teaches that quantitation using internal and external standards is beneficial in assays where the sample matrix affects fluorescence sample quenching (see column 10, lines 1-34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate internal standards or controls as taught by Sunzeri, into the miniaturized chromatographic device taught by Isaka as modified by Northrup, because internal controls or standards in column chromatographic devices are conventional and are standard laboratory practice to those well within ordinary skill.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3-11, 13-32, 34-44, 46, 48-62, 64, and 66-73 have been considered but are moot in view of the new grounds of rejection.

12. Claims 33, 63, 74, and 105-107 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 16, 2003